

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION**

Raquel Gonzalez, et. al. §
Plaintiffs, §
v. §
§
American Medical Systems, Inc.; §
American Medical Systems, Holdings Inc.; §
Endo Pharmaceuticals, Inc.; §
Endo Pharmaceuticals Holdings, Inc.; §
Endo Health Solutions, Inc.; §
C.R. Bard, Inc.; Sofradim Production SAS; §
Tissue Science Laboratories Limited; §
Boston Scientific Corporation; §
Coloplast Corp.; Coloplast A/S; §
Coloplast Manufacturing US, LLC; §
Mentor Worldwide LLC; Porges S.A.; §
Caldera Medical, Inc. §
Johnson & Johnson; Ethicon, Inc.; §
Ethicon, LLC; Atrium Medical Corporation; §
MAQUET Holding GmbH & Co. Kg.; §
CL Medical, Inc.; Cook Medical, Inc.; §
Cook Group, Inc.; Cook Urological, Inc.; §
Neomedic, Inc.; Desarrollo e Investigacion §
Medica Aarogonesa S.L.; §
Neomedic International S.L.; §
Covidien; §
Synovis LifeTechnologies, Inc.; §
Baxter International, Inc.; §
MPathy Medical Devices, Inc.; §
Tyco International LTD; and §
Generic Medical Devices, Inc. §
Defendants. §

CIVIL ACTION NO. 7:13-cv-00457

Plaintiffs' First Amended Complaint

Plaintiffs, as identified in further detail below, bring this action for damages against Defendants, as identified in further detail below, and would show the Court as follows:

I.

Parties

A. Plaintiffs

1. At all relevant times, Plaintiffs resided in the United States of America or its territories. Plaintiffs include women who had Defendants' Mesh Products implanted in their bodies. There are a total of ninety-nine (99) Plaintiffs bringing claims in this action.

2. As a result of Defendants' intentional and coordinated conduct, Plaintiffs were implanted with Defendants' defective and dangerous Mesh Products. Plaintiffs' use of Defendants' Mesh Products caused Plaintiffs' injuries and resulting damages. As pled with additional particularly herein, Defendants' Mesh Products were defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with their use.

3. Plaintiff Raquel Gonzalez is an adult female resident and citizen of Texas.
4. Plaintiff Clarita Dudley is an adult female resident and citizen of Texas.
5. Plaintiff Mary Boggs is an adult female resident and citizen of Texas. Plaintiff Mary Boggs was implanted with an AMS Monarc Subf Hammock Mesh Product and Caldera Desara Mesh Product on or about July 22, 2013 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., Endo Health Solutions, Inc., and Caldera Medical, Inc. for resulting injuries and damages.
6. Plaintiff Rita Smith is an adult female resident and citizen of Texas.
7. Plaintiff Joshlyn Cotton is an adult female resident and citizen of Texas.

8. Plaintiff Maria Herrera is an adult female resident and citizen of Texas.
9. Plaintiff Penny Edwards is an adult female resident and citizen of Texas.
10. Plaintiff Judy Herrington is an adult female resident and citizen of Texas. Plaintiff Judy Herrington was implanted with an Ethicon Obturator Mesh Product on or about January 24, 2005 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC for resulting injuries and damages.
11. Plaintiff Jerri Anne Sanders is an adult female resident and citizen of Texas.
12. Plaintiff Charlene Zakrzewski is an adult female resident and citizen of Texas.
13. Plaintiff Jeanette Barker is an adult female resident and citizen of Texas.
14. Plaintiff Patricia Floyd is an adult female resident and citizen of Texas.
15. Plaintiff Toni Gurganus is an adult female resident and citizen of Texas. Plaintiff Toni Gurganus was implanted with an AMS Sparc Sling Mesh Product on or about May 26, 2004 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.
16. Plaintiff Katrina Baker is an adult female resident and citizen of Nevada.
17. Plaintiff Gypsy Cortner is an adult female resident and citizen of Nevada.
18. Plaintiff Wanda Rowland is an adult female resident and citizen of Nevada.
19. Plaintiff Olivia Torres is an adult female resident and citizen of Nevada. Plaintiff Olivia Torres was implanted with an AMS Perigee Mesh Product on or about December 6, 2006 and brings claims as set forth herein against Defendants

American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

20. Plaintiff Rometta Cameron is an adult female resident and citizen of Nevada. Plaintiff Rometta Cameron was implanted with an Ethicon Prolene Mesh Product on or about October 12, 2009 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC for resulting injuries and damages.

21. Plaintiff Madelynn Talley is an adult female resident and citizen of Ohio.

22. Plaintiff Barbara E. Salsgiver is an adult female resident and citizen of Ohio.

23. Plaintiff Terrie Brown is an adult female resident and citizen of Ohio.

24. Plaintiff Tira L. McPeek is an adult female resident and citizen of Ohio.

25. Plaintiff Roxie Fisher is an adult female resident and citizen of Ohio.

26. Plaintiff Sally Smith is an adult female resident and citizen of Ohio. Plaintiff Sally Smith was implanted with an Boston Scientific Vesica Mesh Product and a Boston Scientific Microvasive Mesh Product on or about January 13, 1999 and brings claims as set forth herein against Defendant Boston Scientific for resulting injuries and damages.

27. Plaintiff Ernestine McDonald is an adult female resident and citizen of Ohio.

28. Plaintiff Ashley Boyer is an adult female resident and citizen of Ohio.

29. Plaintiff Debra Brentlinger is an adult female resident and citizen of Ohio.

30. Plaintiff Sandra Hicks is an adult female resident and citizen of Ohio.

31. Plaintiff Helen Jones-Randol is an adult female resident and citizen of Ohio.

32. Plaintiff Angela Wells is an adult female resident and citizen of Ohio.
33. Plaintiff Ryan Hairston is an adult female resident and citizen of Ohio.
34. Plaintiff Ellen Jones is an adult female resident and citizen of Ohio.
35. Plaintiff Nelya Rutherford is an adult female resident and citizen of Ohio.
36. Plaintiff Vickie Mathews is an adult female resident and citizen of Ohio.
37. Plaintiff Leslie Grant-Robinson is an adult female resident and citizen of Ohio.
38. Plaintiff Cecelia Fussie is an adult female resident and citizen of Ohio.
39. Plaintiff Felecia A. Orr is an adult female resident and citizen of Ohio.
40. Plaintiff Theresa Nelson is an adult female resident and citizen of Ohio.
41. Plaintiff Delores Howard is an adult female resident and citizen of Ohio.
42. Plaintiff Cheryl Ramsey is an adult female resident and citizen of Ohio.
43. Plaintiff Patricia George is an adult female resident and citizen of Ohio. Plaintiff Patricia George was implanted with an Ethicon TVT Mesh Product on or about December 1, 2008 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC for resulting injuries and damages.
44. Plaintiff Helen Holovak is an adult female resident and citizen of Ohio.
45. Plaintiff Geneva Ashworth is an adult female resident and citizen of Ohio. Plaintiff Geneva Ashworth was implanted with an AMS Sparc Sling Mesh Product on or about July 16, 2003 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

46. Plaintiff Janet Mason is an adult female resident and citizen of Ohio.
47. Plaintiff Joyce Hackworth is an adult female resident and citizen of Ohio.
48. Plaintiff Geraldine Dalton is an adult female resident and citizen of Ohio.
49. Plaintiff Janie Hudson is an adult female resident and citizen of Ohio. Plaintiff Janie Hudson was implanted with an Ethicon TVT Mesh Product on or about March 26, 2007 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC for resulting injuries and damages.
50. Plaintiff Linda Tortorice is an adult female resident and citizen of Ohio. Plaintiff Linda Tortorice was implanted with a Mentor ObTape Mesh Product on or about May 20, 2005 and brings claims as set forth herein against Defendant Mentor Worldwide LLC for resulting injuries and damages.
51. Plaintiff Bevlah Apperson is an adult female resident and citizen of Ohio.
52. Plaintiff Dorothy McClain is an adult female resident and citizen of Ohio. Plaintiff Dorothy McClain was implanted with an AMS Monarc Subf Hammock Mesh Product and a AMS Elevate Mesh Product on or about June 2, 2010 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.
53. Plaintiff Nancy Henry is an adult female resident and citizen of Ohio. Plaintiff Nancy Henry was implanted with an AMS Monarc Subf Hammock Mesh Product on or about April 30, 2010 and brings claims as set forth herein against

Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

54. Plaintiff Patricia Adams is an adult female resident and citizen of Ohio. Plaintiff Patricia Adams was implanted with an AMS Sparc Sling Mesh Product on or about June 21, 2004 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

55. Plaintiff Mary Engle is an adult female resident and citizen of Ohio.

56. Plaintiff Hester Williams is an adult female resident and citizen of Ohio.

57. Plaintiff Sharon Wilson is an adult female resident and citizen of Ohio. Plaintiff Sharon Wilson was implanted with an AMS Elevate Mesh Product on or about February 5, 2010 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

58. Plaintiff Debra L. Brown is an adult female resident and citizen of Ohio.

59. Plaintiff Claudia Howard is an adult female resident and citizen of Ohio. Plaintiff Claudia Howard was implanted with an Boston Scientific Xeneform Mesh Product on or about October 25, 2006 and brings claims as set forth herein against Defendant Boston Scientific for resulting injuries and damages.

60. Plaintiff Cheryl Zurinsky is an adult female resident and citizen of Ohio.

61. Plaintiff Katie Day is an adult female resident and citizen of Ohio.
62. Plaintiff Cheryl Cassada is an adult female resident and citizen of Ohio.
63. Plaintiff Mary Ann Davis is an adult female resident and citizen of Ohio. Plaintiff Mary Ann Davis was implanted with an Ethicon Prolene Mesh Product Ethicon TVT Mesh Product on or about August 24, 2009 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC for resulting injuries and damages.
64. Plaintiff Lois Alexander is an adult female resident and citizen of Ohio.
65. Plaintiff Patricia Poppinger is an adult female resident and citizen of Ohio.
66. Plaintiff Billie Fleming is an adult female resident and citizen of Ohio.
67. Plaintiff Terri L. Neil is an adult female resident and citizen of Ohio. Plaintiff Terri L. Neil was implanted with a Coloplast Aris Mesh Product on or about August 1, 2012 and brings claims as set forth herein against Defendants Coloplast Corp.; Coloplast A/S, Coloplast Manufacturing US, LLC, Mentor Worldwide LLC, and Porges S.A. for resulting injuries and damages.
68. Plaintiff Gwendolyn Mullins is an adult female resident and citizen of Ohio. Plaintiff Gwendolyn Mullins was implanted with an Ethicon TVT Mesh Product on or about June 17, 2005 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC for resulting injuries and damages.
69. Plaintiff Vanessa Dixon is an adult female resident and citizen of Ohio.
70. Plaintiff Keita Cotner is an adult female resident and citizen of Ohio.
71. Plaintiff Marjorie Heilbock is an adult female resident and citizen of Ohio.

72. Plaintiff Deborah Blake is an adult female resident and citizen of Ohio.
73. Plaintiff Judith Williamson is an adult female resident and citizen of Ohio. Plaintiff Judith Williamson was implanted with a Bard Align Mesh Product on or about April 29, 2009 and brings claims as set forth herein against Defendants C.R. Bard, Inc., Sofradim Production SAS, and Tissue Science Laboratories Limited for resulting injuries and damages.
74. Plaintiff Lori Bean is an adult female resident and citizen of Ohio.
75. Plaintiff Brenda Bradds is an adult female resident and citizen of Ohio. Plaintiff Brenda Bradds was implanted with an AMS MiniArc Precise Mesh Product on or about July 18, 2011 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.
76. Plaintiff Jacquelyn Brown is an adult female resident and citizen of Ohio.
77. Plaintiff Mary Erickson is an adult female resident and citizen of Ohio.
78. Plaintiff Jacquelyn Hannah is an adult female resident and citizen of Ohio. Plaintiff Jacquelyn Hannah was implanted with an AMS Monarc Subf Hammock Mesh Product on or about November 7, 2008 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

79. Plaintiff Judy Kraft is an adult female resident and citizen of Ohio. Plaintiff Judy Kraft was implanted with an Ethicon Physiomesh Mesh Product on or about November 18, 2011 Bard Soft Mesh Product on or about November 2, 2012 and brings claims as set forth herein against Defendants Johnson & Johnson, Ethicon, Inc., Ethicon, LLC, C.R. Bard, Inc., Sofradim Production SAS, and Tissue Science Laboratories Limited for resulting injuries and damages.

80. Plaintiff Barbara McCombs is an adult female resident and citizen of Ohio. Plaintiff Barbara McCombs was implanted with an AMS MiniArc Single Incision Mesh Product on or about July 30, 2008 and a AMS Elevate Mesh Product on or about April 1, 2013 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

81. Plaintiff Janet Prater is an adult female resident and citizen of Ohio.

82. Plaintiff Beatrice Scott is an adult female resident and citizen of Ohio.

83. Plaintiff Annette Stone is an adult female resident and citizen of Ohio.

84. Plaintiff Renee M. Despain is an adult female resident and citizen of Oklahoma. Plaintiff Renee M. Despain was implanted with an AMS Sparc Sling Mesh Product on or about September 22, 2009 and brings claims as set forth herein against Defendants American Medical Systems, Inc., American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions, Inc. for resulting injuries and damages.

85. Plaintiff Charnell Temple is an adult female resident and citizen of Oklahoma.
86. Plaintiff Shirley Crosby is an adult female resident and citizen of Oklahoma.
87. Plaintiff Kimberly Long is an adult female resident and citizen of Oklahoma.
88. Plaintiff Lisa M. Anderson is an adult female resident and citizen of Oklahoma.
Plaintiff Lisa M. Anderson was implanted with a Boston Scientific Lynx Mid Urethral Sling Mesh Product on or about January 11, 2007 and brings claims as set forth herein against Defendants Boston Scientific Corporation for resulting injuries and damages.
89. Plaintiff Shelly Threlkeld is an adult female resident and citizen of Oklahoma.
90. Plaintiff Shanda Raleigh is an adult female resident and citizen of Oklahoma.
91. Plaintiff Penella Cline is an adult female resident and citizen of Oklahoma.
92. Plaintiff Julie Fox is an adult female resident and citizen of Oklahoma.
93. Plaintiff Jackie Sherrill is an adult female resident and citizen of Oklahoma.
94. Plaintiff Tena Ellis is an adult female resident and citizen of Oklahoma.
95. Plaintiff Karen Kelly is an adult female resident and citizen of Oklahoma.
96. Plaintiff Phyllis Stevenson is an adult female resident and citizen of Oklahoma.
97. Plaintiff Lisa Price is an adult female resident and citizen of Oklahoma.
98. Plaintiff Brenda Hicks is an adult female resident and citizen of Oklahoma.
99. Plaintiff Ra'Shawnda Johnson is an adult female resident and citizen of Oklahoma.
100. Plaintiff Sharon Poole is an adult female resident and citizen of Oklahoma.
101. Plaintiff Tracey Verdun is an adult female resident and citizen of Oklahoma.

B. Defendants

102. American Medical Systems, Inc. (“AMS”) is a Delaware Corporation with its headquarters and principal place of business in Minnetonka, Minnesota.

103. AMS is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc. (“AMS Holdings”) which is in turn is a wholly owned subsidiary of Defendants Endo Pharmaceuticals, Inc. (“Endo”) which is in turn a wholly owned subsidiary of Defendant Endo Pharmaceuticals Holdings Inc. (“Endo Holdings”) and Defendant Endo Health Solutions Inc. (“EHS”) and are Delaware corporations.

1. Defendant AMS Holdings is the parent of wholly owned subsidiary AMS and is a Delaware corporation.

2. Defendant Endo is a Delaware corporation, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania.

3. Defendant Endo Holdings is a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo Holdings was the parent of wholly owned subsidiary, Endo.

4. Defendant Endo Holdings changed its name to Endo Health Solutions, Inc. (“EHS”).

5. Defendant EHS is a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317 and is the parent of AMS and AMS Holdings.

6. Defendant EHS has aggregated four operating businesses into one enterprise including AMS and AMS Holdings. At all relevant times, defendant Endo merged with AMS and as part of that acquisition, purchased and assumed all liability relating to legal claims arising from the implantation of the Mesh Products in question.

7. Defendants AMS is a citizen of Minnesota and Delaware.
8. Defendant AMS Holdings is a citizen of Delaware.
9. Defendant Endo is a citizen of Delaware and Pennsylvania.
10. Defendant Endo Holdings is a citizen of Delaware and Pennsylvania.
11. Defendant EHS is a citizen of Delaware and Pennsylvania
12. Defendant C.R. Bard, Inc. (“Bard”) is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Bard as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.
13. Sofradim Production SAS (“Sofradim”) is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Sofradim as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.
14. Tissue Science Laboratories Limited (“TSL”) is a British private limited company with its principal place of business in the United Kingdom. All acts and omissions of TSL as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.
15. Defendants Bard is a citizen of New Jersey.
16. Boston Scientific Corporation is a Delaware corporation with its corporate headquarters in Boston, Massachusetts.
17. Defendant Boston Scientific is a citizen of Delaware and Massachusetts.
18. Defendant Coloplast Corp. (“Coloplast Corp.”) is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at

1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. is a wholly owned U.S. sales and marketing subsidiary of Coloplast A/S, a Denmark corporation.

19. Defendant Mentor Worldwide LLC (“Mentor Worldwide”) is a Delaware limited liability company with its principal place of business in California. Mentor Worldwide’s sole member is Ethicon, Inc. Ethicon, Inc. is a wholly owned subsidiary of Johnson & Johnson located in Somerville, New Jersey.

20. Defendant Coloplast A/S is a corporation organized and existing under the laws of the Kingdom of Denmark maintaining its principal place of business at Holtedam 1, Humlebaek 3050, Kingdom of Denmark.

21. Defendant Coloplast Manufacturing US, LLC is a limited liability corporation organized and existing under Delaware, law maintaining its principal place of business as 1940 Commerce Drive, North Mankato, MN 56002. Its registered office is 560 Park Street, #6, St. Paul, Minnesota 55103. Coloplast Manufacturing US, LLC is a wholly-owned subsidiary of Coloplast Corp.

22. Defendant Porges S.A. (“Porges”) is a corporation organized and existing under the laws of the France maintaining its principal place of business at Centre d'affaires La Boursidière 92357 Le Plessis-Robinson cdx., France.

23. Defendant, Ethicon, Inc. is a New Jersey corporation that maintains its principle place of business in Somerville, New Jersey.

24. Defendant Coloplast Corp. is a citizen of Delaware and Minnesota.

25. Defendant Mentor Worldwide LLC is a citizen of Delaware and California.

26. Defendant Ethicon, Inc. is a citizen of New Jersey.

27. Defendant Caldera Medical, Inc. is a California Corporation with its principal place of business in California.

28. Defendant Caldera Medical, Inc. is referred to herein as Defendant.

29. Defendant Caldera Medical, Inc. is a citizen of California.

30. Defendant Johnson & Johnson (“J&J”) is a New Jersey corporation with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its’ Mesh Products as described herein.

31. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are “Business Units” including the “Ethicon Franchise.” The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the Mesh Products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

32. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant J&J which maintains its principle place of business in Somerville, New Jersey.

33. Defendant, Ethicon, LLC, is a wholly owned subsidiary of Johnson & Johnson Medical, Inc., with its principle place of business in San Lorenzo, Puerto Rico. Ethicon LLC was charged by J&J with the manufacture of Ethicon Inc.’s Mesh Products.

34. Defendants J&J, Ethicon, Inc., and Ethicon, LLC are collectively referred to herein as Defendants.

35. Defendant J&J is a citizen of New Jersey.

36. Defendant Ethicon, Inc. is a citizen of New Jersey.

37. Defendant Ethicon, LLC is a citizen of New Jersey.

38. Defendant Atrium Medical Corporation (“Atrium”) is a Delaware corporation which maintains its headquarters and principal place of business in New Hampshire. Atrium is a wholly owned subsidiary of MAQUET Holding GmbH & Co. Kg. which operated under the name MAQUET Getinge Group.

39. Defendant MAQUET Holding GmbH & Co. Kg. (“MAQUET”) is a German corporation which maintains its headquarters and principal place of business in Kehler Strasse 31, 76437 Rastatt, Germany.

40. Defendant Atrium is a citizen of Delaware and New Hampshire

41. Defendant CL Medical, Inc. (“CL Medical”) is a Delaware corporation which maintains its headquarters and principal place of business in Massachusetts.

42. Defendant CL Medical is a citizen of Delaware and Massachusetts.

43. Defendant Cook Medical, Inc. is a Delaware corporation which maintains its headquarters and principal place of business in Indiana.

44. Defendant Cook Group, Inc. is a Delaware corporation which maintains its headquarters and principal place of business in Indiana.

45. Defendant Cook Urological, Inc. is a Delaware corporation which maintains its headquarters and principal place of business in Indiana.

46. Defendant Cook Medical, Inc. is a citizen of Delaware and Indiana.

47. Defendant Cook Group, Inc. is a citizen of Delaware and Indiana.
48. Defendant Cook Urological, Inc. is a citizen of Delaware and Indiana.
49. Defendant Neomedic , Inc.is a Delaware corporation
50. Defendant Desarrollo e Investigacion Medica Aargonesa S.L. is a foreign corporation which maintains it headquarters and principal place of business in Zaragoza, Spain.
51. Defendant Neomedic International S.L. is a foreign corporation which maintains it headquarters and principal place of business in Barcelona, Spain.
52. Defendant Neomedic, Inc. is a citizen of Delaware.
53. Defendant Covidien is a publicly traded foreign company which maintains its headquarters and principal place of business in Massachusetts.
54. Defendant Covidien is a citizen of Massachusetts.
55. Defendant Synovis Life Technologies, Inc. (“SLT”) is a Minnesota corporation which maintains its headquarters and principal place of business in Minnesota.
56. Defendant Baxter International, Inc. (“Baxter”) Delaware Corporation and parent company of Defendant SLT.
57. Defendant SLT is a citizen of Minnesota.
58. Defendant Baxter is a citizen of Delaware.
59. Defendant MPathy Medical Devices, Inc. (“MPathy”) is a Delaware corporation. Defendant MPathy was acquired by Defendant Coloplast on or about October 29, 2010.
60. Defendant MPathy is a citizen of Delaware.
61. Defendant Tyco International LTD (“Tyco”) is a foreign publically traded entity.
62. Defendant Generic Medical Devices, Inc. (“GMD”) is a Delaware corporation which maintains its headquarters and principal place of business in Washington.

63. Defendant GMD is a citizen of Delaware and Washington.
64. Defendants AMS, AMS Holdings, Endo, Endo Holdings, EHS, Bard, Sofradim, TSL, Boston Scientific, Coloplast Corp., Coloplast A/S, Coloplast Manufacturing US, LLC, Mentor Worldwide LLC, Porges S.A., Ethicon, Inc., Caldera Medical, Inc., J&J, Ethicon, LLC, Atrium, MAQUET, CL Medical, Cook Medical, Inc., Cook Group, Inc., Cook Urological, Inc., Neomedic, Inc., Desarrollo e Investigacion Medica Aarogonesa S.L., Neomedic International S.L., Covidien, Synovis, Baxter, MPathy, Tyco International LTD, and GMD are collectively referred to herein as “Defendants”.
65. Defendants designed, manufactured, packaged, labeled, marketed, sold, and distributed the transvaginal mesh products at issue in this matter (collectively referred to herein as “Defendants’ Mesh Products” or “Mesh Products”).

II.

Jurisdiction & Venue

66. Jurisdiction in this Court is proper as Defendants do business in the state of Texas and committed torts in whole or in part against Plaintiffs in Texas. Furthermore, based upon information and belief, the materials and/or component parts used to manufacture Defendants’ Mesh Products were produced, processed, supplied, and/or distributed by Texas facilities and/or by entities located and/or doing business in Texas.

67. Based upon information and belief, at all relevant times, Defendants and the Texas based producers, processors, suppliers, and/or distributors of the materials and/or component parts used in Defendants’ Mesh Products knew or should have known that the materials and/or component parts used to manufacture Defendants’ Mesh Products were unsafe for use in humans and unfit for the medical applications at issue in this suit.

68. Venue is proper in this Court pursuant to Tex. Civ. Prac. Rem. Code § 15.002 because all or a substantial part of the events or omissions giving rise to the claim occurred in Hidalgo County and one or more of the Plaintiffs resided in Hidalgo County at the time of the accrual of the cause of action. TEX. CIV. PRAC. REM CODE § 15.002. In addition, one or more of the named Plaintiffs were implanted with Defendants' Mesh Products, and/or were injured in this County.

69. At all times material to this action, Defendants and/or their predecessors in interest and/or its subsidiaries, regularly engaged in business in Texas and Hidalgo County, including advertising, analyzing, assembling, designing, developing, distributing, inspecting, labeling, manufacturing, marketing, packaging, producing, processing, promoting, researching, selling, testing, and/or training in the use of the Mesh Products.

70. Defendants regularly solicit and transact business in, receive substantial revenues from, and/or distribute products in Texas and Hidalgo County.

71. It was reasonably foreseeable to Defendants that the Mesh Products would be used on patients such as Plaintiffs and in the state of Texas and Hidalgo County.

72. At all relevant times, Defendants transacted business in the state of Texas and Hidalgo County.

73. At all relevant times, Defendants committed tortious conduct within the state of Texas and Hidalgo County.

74. At all relevant times, Defendants used or possessed property situated in the state of Texas and Hidalgo County.

75. At all relevant times, Defendants marketed, promoted, and sold their Mesh Products throughout the state of Texas and Hidalgo County.

76. Defendants' contacts with the state of Texas and Hidalgo County were at all relevant times, systematic and continuous such that the exercise of jurisdiction comports with the notions fair play and substantial justice.

77. Maintaining venue in Hidalgo County, Texas does not unfairly prejudice any party to this suit. Further, there is an essential need to have Plaintiffs' claims tried in Hidalgo County and Hidalgo County is a fair and convenient venue for Plaintiffs and all parties against whom suit has been brought.

78. Additionally, some Plaintiffs named herein, were implanted with and suffered injury as a direct and proximate result of Defendants' Mesh Products and/or Defendants' acts and/or omissions in the state of Texas and Hidalgo County.

79. Plaintiffs do not assert claims or rights arising under the Constitution, treaties, or laws of the United States; thus, there is no federal question at issue pursuant to 28 U.S.C. §1441(b) and 28 U.S.C. §1331.

80. Complete diversity of citizenship is lacking pursuant to 28 U.S.C. §1441(b) and 28 U.S.C. §1332(c) as certain Plaintiffs and Defendants are citizens of the same state.

81. Plaintiffs' claims are brought pursuant to state law. As such, there is no federal subject matter jurisdiction because no federal question is raised and complete diversity does not exist.

82. Plaintiffs' claims present common questions of fact and law concerning, as alleged herein, what information Defendants possessed concerning the harmful effects of the Mesh Products, what information Defendants chose to disclose, and what information Defendants were required by law to disclose about those harmful effects.

83. Plaintiffs' claims are logically related because all Plaintiffs allege the same claims related to their use of Mesh Products. Further, these Mesh Products were defectively designed, manufactured, marketed and sold by Defendants, and Defendants failed to provide appropriate warnings and instructions regarding the dangers posed by these Mesh Products.

84. Defendants' conduct, which resulted in Plaintiffs' injuries, is common to all Plaintiffs and includes, but is not limited to, Defendants' failure to conduct adequate safety and efficacy testing, Defendants' submissions to the regulatory agency that indicated that the Mesh Products were the substantial equivalent to pre-existing and previously approved devices, Defendants marketing materials and literature, and Defendants' failure to provide adequate warnings regarding the risks associated with Defendants' Mesh Products.

85. Defendants' conduct in designing, developing, marketing, and distributing these products relates to all Plaintiffs and provides a common universe of facts underlying Plaintiffs' claims, such that Plaintiffs' claims against Defendants arise from the same transaction or occurrence or the same series of transactions or occurrences.

86. Plaintiffs suffered injuries and damages following the implant and common liability facts will be presented to demonstrate that Defendants' knew or should have known that their Mesh Products cause such serious complications and injuries.

87. Discovery will be identical for all Plaintiffs' claims with respect to Defendants' conduct and regulatory violations, as all claims arise out of the same acts and/or omissions of Defendants and involve common questions of law and/or fact.

88. Joinder of Plaintiffs' claims is proper because Plaintiffs' claims arise out of the same acts and/or omissions of Defendants and involve common questions of law and/or fact.

89. This is an action for damages that exceed the minimum jurisdictional limits of this Court.

90. Plaintiffs have timely filed this lawsuit within the applicable statutory limitations period.

91. All conditions precedent have been satisfied or have occurred.

92. Plaintiffs' claims are not removable to federal court on the basis of diversity jurisdiction, federal question jurisdiction, or any other jurisdictional basis, any attempt to remove this matter would be improper and would provide grounds for sanctions.

III.

Tolling of Statute Of Limitations

93. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

94. Despite diligent investigation by Plaintiffs into the cause of their injuries, the nature of Plaintiffs' injuries and damages and their relationship to the Mesh Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed within the applicable statutory limitations period.

95. Further, the running of the statute of limitations in this cause is tolled under the doctrine of equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' concealment of the true risks associated with the use of the Mesh Products. Plaintiffs could not have reasonably discovered the wrongdoing. As a

direct and proximate result of Defendants' concealment, the Plaintiffs suffered severe injuries and damages.

IV.

General Allegations

96. At all relevant times, Defendants designed, patented, tested, manufactured, labeled, marketed, sold, and distributed the Mesh Products in question. Defendants' Mesh Products were designed primarily for the purposes of treating pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI").

97. POP is a condition that results from weakened or stretched tissues that support the female pelvic organs. When treating POP, the Mesh Products are usually implanted vaginally to reinforce the vaginal wall.

98. SUI is a medical condition involving involuntary leakage of urine during moments of physical activity. When treating SUI, Defendants' Mesh Products are usually implanted vaginally to support a patient's urethra.

99. Surgical mesh products have been used to repair abdominal hernias for decades. In the 1990's surgeons began using surgical mesh for the treatment of POP and SUI. At or near that time, Defendants began to modify the mesh previously used for abdominal hernia repairs to be used as products specifically marketed for the surgical treatment of POP and SUI. Defendants began marketing these Mesh Products along with the tools and appurtenances used for pelvic area tissue insertion and fixation.

100. Defendants' Mesh Products are targeted for use in women who suffer from POP and/or SUI. Defendants' Mesh Products are composed of biologic and/or non-absorbable synthetic. Despite Defendants' claims that the materials used in their Mesh

Products are inert, the scientific evidence indicates that this material is biologically incompatible with human tissue and promotes a negative immune response and/or inflammation of pelvic tissue in a large subset of patients frequently resulting in significant adverse events, severe injuries, and debilitating medical complications.

101. Further, the collagen components of Defendants' Mesh Products cause hyper-inflammatory responses leading to medical problems including, but not limited to, chronic pain and fibrotic reaction. Defendants Mesh Products cause chronic pain, fibrotic reaction, disability, and infection resulting from hyper-inflammatory responses to Defendants' Mesh Products.

102. Defendants' Mesh Products cause erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence in addition to complications at the time of insertion, which included the perforation of the bowel, bladder, and blood vessels. In addition, Defendants' Mesh Products degrade, fragment, shrink, migrate, and fold after implantation.

103. Defendants' Mesh Products are biologically incompatible with human tissue and stimulate a negative immune response in patients. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiffs.

104. Despite having knowledge of these serious side effects, Defendants have continued to market the Mesh Products as safe treatment options for POP and SUI.

105. At all relevant times, Defendants knew or should have known of the risks and complications associated with Defendants' Mesh Products. Defendants knew or should have known that the Mesh Products unreasonably exposed patients to the risk of serious harm

while conferring no benefit over available feasible alternatives that do not involve the same risks.

106. At all relevant times, Defendants possessed the knowledge, the means, and the duty to adequately warn regarding the risks associated with the Mesh Products.

107. At all relevant times, Defendants, their agents, servants, and employees acting in the course and scope of their employment, negligently and recklessly breached their duty to adequately warn regarding the risks associated with the Mesh Products.

108. At all relevant times, Defendants knew or should have known that the Mesh Products exposed Plaintiffs to unreasonable risk while failing to provide significant improvement in clinical outcomes over alternative treatments which were equally or more effective and did not involve the same risk.

109. Despite having extensive knowledge of the extreme risks associated with the use of the Mesh Products, as well as the absolute duty to properly and adequately warn foreseeable users, Defendants failed to adequately warn of the risks associated with the Mesh Products.

110. Defendants knew of the dangerous side effects associated with the Mesh Products. Defendants failed to properly evaluate the risk profile of the Mesh Products or did not properly publish, disclose, and/or disseminate the results of the testing and studies it did conduct. Defendants failed to adequately warn or remedy the risks associated with the Mesh Products, but instead concealed, suppressed and failed to disclose the dangers.

111. Defendants omitted the risks, dangers, defects, and disadvantages of the Mesh Products, and advertised, promoted, marketed, sold and distributed the Mesh Products as safe medical devices when Defendants knew or should have known that the Mesh Products were

not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems for Plaintiffs.

112. Contrary to Defendants' representations and marketing, Defendants' Mesh Products have significantly high rates of failure, injury, and complications, fail to perform as intended, and have caused severe and irreversible injuries to Plaintiffs.

113. Defendants failed to adequately disclose, report, and/or disseminate information regarding the propensity of the Mesh Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Mesh Products through various means and media. Defendants have also underreported information about the injuries caused by the use of the implantation kits and instructions that accompany Defendants' Mesh Products.

114. Defendants failed to adequately test and evaluate the risks and benefits of Defendants' Mesh Products. Further, Defendants failed to design and establish a safe, effective procedure for removal of the Mesh Products, or to determine if a safe, effective procedure for removal of the Mesh Products exists.

115. At all relevant times, feasible, suitable, safer, and more effective alternatives to the Mesh Products existed.

116. At all relevant times, Defendants continued to promote the Mesh Products as safe and effective having conducting no clinical trials to support the efficacy and safety of the Mesh Products.

117. Defendants failed to disclose, train, or disseminate information about the known risks and failed to warn of dangers and risks associated with the Mesh Products of which Defendants knew or should have known.

118. Defendants failed to provide adequate warnings, training, and instructions about the dangers and adverse effects caused by the Mesh Products. Defendants' Mesh Products were defective as marketed due to inadequate warnings, training instructions, labeling and/or inadequate testing.

119. Defendants' Mesh Products were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

120. Defendants' Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants.

121. The injuries, conditions, and complications suffered by those implanted with Defendants' Mesh Products were foreseeable consequences of Defendants' conduct and the dangerous and defective nature of Defendants' Mesh Products.

122. As a direct and proximate result of Defendants' Mesh Products and/or Defendants' negligence, negligence per se, defective design, defective manufacture, failure to warn, breach of implied warranties, and/or gross negligence, Plaintiffs have suffered and will continue to suffer severe injuries and damages as further described herein.

V.

Plaintiffs' Mesh Implants & Resulting Injuries

123. Plaintiffs incorporate by reference all the above paragraphs as if set forth in full herein.

124. Plaintiffs bring this action to recover damages resulting from injuries suffered as a direct and proximate result of the implantation of Defendants' Mesh Products.

125. Plaintiffs' use of Defendants' Mesh Products caused Plaintiffs' injuries and resulting damages. During Plaintiffs' procedures, Defendants' Mesh Products were used in a manner reasonably foreseeable to Defendants. Defendants' Mesh Products were defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with the Mesh Products use at the time of their implantation in Plaintiffs.

126. Plaintiffs have suffered serious injuries and damages as a direct and proximate result of Defendants' Mesh Products. Plaintiffs' injuries necessitate continued medical treatment for the foreseeable future.

127. Prior to Plaintiffs' respective surgeries, Defendants knew or should have known of the risks associated with implantation of the Mesh Products and possessed the means to provide adequate warning regarding the risks associated with Defendants' Mesh Products. Had Plaintiffs been adequately warned that Defendants' Mesh Products could cause serious side effects, they would have not have undergone treatment involving Defendants' Mesh Products.

128. As a direct and proximate result of Defendants' conduct, Plaintiffs and Plaintiffs' implanting physicians, were unaware, and could not reasonably know, or through the exercise of reasonable diligence could not have known, that the Mesh Products exposed Plaintiffs to the risks and injuries alleged herein.

129. As a direct and proximate result of Defendants' conduct, Plaintiffs suffered physical injuries and damages. Further, the Plaintiffs have sustained in the past, and will sustain in the future, pain and suffering, mental anguish, emotional distress, disfigurement, physical impairment, embarrassment and humiliation, psychological injury, a reasonable and

traumatic fear of an increased risk of additional injuries, progression of existing conditions, and other serious injury and loss.

130. Plaintiffs also have suffered and will sustain past and future general and special damages, including past and future medical care and treatment, lost wages, and lost earning capacity.

131. As a direct and proximate result of Defendants' conduct and/or Defendants' Mesh Products, Plaintiffs have incurred, and will continue to incur for the foreseeable future, medical, nursing, diagnostic, hospital, pharmaceutical, rehabilitative, and other related costs and expenses for Plaintiffs' treatment and care, along with lost wages, lost earning capacity, and other damages for which they are entitled to compensation.

132. Plaintiffs are entitled to punitive damages because Defendants' conduct was reckless and without regard for the Plaintiffs' and the public's safety and welfare. Defendants misled both the medical community and the public at large, including the Plaintiffs, by making false representations about the safety of the Mesh Products. Defendants downplayed, understated and/or disregarded its knowledge of the serious risks associated with the Mesh Products. Nevertheless, Defendants continued to market the Mesh Products by providing false and misleading information with regard to their safety and efficacy. Defendants' conduct constitutes a willful, despicable, fraudulent, malicious, oppressive, reckless, and conscious disregard for the rights of Plaintiffs and the public.

133. Defendants are liable both jointly and severally to the Plaintiffs for all damages, punitive damages, and all other relief to which Plaintiffs are entitled to by law or equity.

VI.

Plaintiffs' Causes Of Action

134. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

135. Plaintiffs set forth the following claims in the alternative, such that the sufficiency of this Complaint shall not be defeated by an inconsistency or insufficiency among any one or more of the alternative claims set forth herein.

Count I: Negligence & Negligence Per Se

136. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

137. At relevant times, Defendants had a duty to Plaintiffs to exercise reasonable care in designing, manufacturing, marketing, labeling, packaging, sale, and distribution of Defendants' Mesh Products.

138. Defendants are liable to Plaintiffs as a result of Defendants' negligent advertising, analyzing, assembling, designing, developing, distributing, inspecting, labeling, manufacturing, marketing, packaging, patenting, producing, processing, promoting, selling, testing, and/or training in the use of Defendants' Mesh Products.

139. Defendants were under a duty to exercise reasonable care in advertising, analyzing, assembling, designing, developing, distributing, inspecting, labeling, manufacturing, marketing, packing, producing, promoting, processing, researching, selling, and testing the Mesh Products.

140. Defendants owed a duty to adequately warn of the risks, dangers, and adverse effects associated with the use of Defendants' Mesh Products.

141. Defendants negligently and carelessly breached the above-described duties to

Plaintiffs by:

- a. Failing to design and manufacture the Mesh Products without defects that would result in an unreasonable risk of harm to patients implanted with the Mesh Products;
- b. Failing to exercise reasonable care in testing the Mesh Products prior to marketing, sale, and distribution of the Mesh Products so as to avoid unreasonable risk of harm and injury to patients implanted with the Mesh Products;
- c. Failing to exercise reasonable care in inspecting the Mesh Products prior to distribution to avoid the implantation of the defective Mesh Products in women and exposing them to unreasonable risk or harm.
- d. Failing to ensure the Mesh Products warnings to the medical community, physicians, the Plaintiffs' physicians, and Plaintiffs were accurate and adequate, despite having extensive knowledge of the risks associated with the Mesh Products;
- e. Failing in their obligation to provide relevant information, data and warnings regarding the adverse health risks associated with exposure to the Mesh Products, and/or that there existed safer and more or equally effective alternative methods or treatment options;
- f. Failing to conduct post market safety surveillance and report that information;
- g. Failing to include adequate warnings and/or provide adequate and clinically relevant information;
- h. Failing to continually monitor, test, and analyze data regarding safety, efficacy, and the implantation practices for the Mesh Products;
- i. Failing to review all adverse product event information and to report any information bearing upon the adequacy and/or accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by the Mesh Products to the appropriate parties;

- j. Failing to provide adequate post-marketing warnings and instructions;
- k. Failing to disclose the results of the testing and other information in their possession regarding the possibility that the Mesh Products can cause serious and catastrophic side effects;
- l. Failing to adequately warn about the dangers of using the Mesh Products;
- m. Promoting and marketing the Mesh Products as safe and effective for use with women when, in fact, they were unsafe;
- n. Failing to act as a reasonably prudent product manufacturer in advertising, analyzing, assembling, designing, developing, distributing, inspecting, labeling, manufacturing, marketing, packaging, producing, processing, promoting, researching, selling, testing, and/or training in the use of the Mesh Products;
- o. Failing to perform adequate and necessary studies to determine and analyze the safety and risks associated with the safety and efficacy of the Mesh Products' use;
- p. Continuing to promote the safety and effectiveness of the Mesh Products, while downplaying their risks, even after Defendants knew or should have known of the risks of the Mesh Products;
- q. Negligently and carelessly promoting the Mesh Products as safe and effective for use with women when, in fact, they were unsafe;
- r. Negligently and carelessly over-promoting the Mesh Products in a zealous and unreasonable way, without regard to the potential danger that they posed to patients; and
- s. Negligently and carelessly failing to act as a reasonably prudent product manufacturer, distributor, marketer, promoter, or seller would under same or similar circumstances.

142. In addition, Defendants' negligence and negligence per se resulted in the negligent design and/or manufacture of Defendants' Mesh Products.

143. Defendants negligently failed to instruct and warn Plaintiffs and/or Plaintiffs' physicians, hospitals, health care professionals, and the general public regarding the risks associated with Defendants' Mesh Products. Specifically, Defendants did not provide sufficient or adequate warnings regarding:

- a. The tendency of the Mesh Products to shrink, migrate, fragment, degrade and deform following implantation;
- b. The propensity of the Mesh Products to cause patients chronic infections;
- c. The propensity of the Mesh Products to require corrective surgery to remove or modify the placement of the Mesh Products;
- d. The Mesh Products design defects outlined herein;
- e. The increased risks associated with the Mesh Products when compared to equally or more effective alternative treatment options;
- f. The increased risk of complications associated with future corrective surgeries following implantation of the Mesh Products when compared to equally or more effective alternative treatment options;
- g. The increased risk for multiple future surgeries;
- h. The tendency of Mesh Products to extrude and erode;
- i. The propensity of Mesh Products to cause chronic infection and recurrent, intractable, and chronic pain;
- j. The propensity of the Mesh Products to cause permanent scarring in the vaginal and pelvic region, following implantation;
- k. The design defects of the Mesh Products which inhibit proper mating with the pelvic and vaginal tissues;
- l. The propensity of the Mesh Products to cause severe complications and expose patients to many health hazards;

- m. The propensity of removal of the Mesh Products to necessitate additional surgeries, exposing the patient to greater risk; and/or
- n. The risk that complete removal of the Mesh Products may not remedy the health issues of the patient.

144. Defendants knew or should have known that consumers, such as Plaintiffs, would suffer injury as a result of Defendants' failure to exercise ordinary care, as described above.

145. Defendants' conduct described herein constitutes negligence *per se*.

146. As a direct and proximate result of Defendants' negligence and negligence *per se*, Plaintiffs have sustained permanent injuries and damages as set forth herein.

Count II: Strict Liability – Design Defect

147. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

148. Defendants are strictly liable to Plaintiffs for injuries and damages suffered as result of the defective design of the Mesh Products.

149. At all relevant times, Defendants' Mesh Products were not reasonably safe for their intended uses and were defectively designed.

150. Defendants manufactured, marketed, promoted, distributed, and sold the Mesh Products in the stream of commerce despite the design defects that Defendants knew or should have known of.

151. Defendants' Mesh Products are defectively designed when compared to safer non-vaginal mesh alternative treatments. Patients who were implanted with Defendants'

Mesh Products are exposed to a number of dangerous defects which include, but are not limited to:

- a. The Mesh Products cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- b. The materials used in the Mesh Products cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- c. The design of the Mesh Products and/or implantation kits requires implantation into and through an area of the body with high levels of bacteria that can adhere to the mesh and/or can injure nerves in the pelvic region causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- d. The design of the Mesh Products increase the likelihood of contracture, shrinkage, erosion, and/or folding causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- e. The design of the Mesh Product increases the risk of movement, elongation, and/or deformity after implantation causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- f. The design of the Mesh Products increases the risk of improper mating to the delicate and sensitive areas where they are implanted causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- g. The design of the Mesh Products increases the risk of degradation, erosion, and/or fragmentation causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;

- h. The disintegration of and hyper-inflammatory responses to the collagen components of the Mesh Products cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- i. The hardening of the Mesh Products following implantation cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae; and/or
- j. The design of the Mesh Products creates a non-anatomic condition in the pelvis causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae.

152. Defendants knew and intended that consumers, including Plaintiffs, would use the Mesh Products, without any inspection for defects, and those using the Mesh Products would rely upon the representations made by Defendants.

153. Prior to the manufacture, sale, and distribution of the Mesh Products, Defendants knew, or should have known, that the Mesh Products were defectively designed.

154. The Mesh Products were used for the intended purpose and the dangerous defects could not have been discovered through the exercise of due care.

155. At the time that Defendants manufactured, marketed, promoted, distributed, and sold the Mesh Products, there existed safer and more or equally effective alternative treatment methods.

156. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging, selling and/or distributing the defectively designed Mesh Products.

157. As a direct and proximate result of Defendants' defective design of the Mesh Products, Plaintiffs have sustained permanent injuries and damages as set forth herein.

Count III: Strict Liability – Manufacturing Defect

158. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

159. Defendants are strictly liable to Plaintiffs for injuries and damages suffered as result of the defective manufacture of the Mesh Products.

160. At all relevant times, Defendants' Mesh Products were not reasonably safe for their intended uses and were defectively manufactured.

161. Defendants' Mesh Products were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture. These manufacturing defects pose unreasonable risks of serious bodily harm to Plaintiffs.

162. Defendants knew that the Mesh Products would be used by Plaintiffs without inspection for defects, and that there was a reasonable expectation that Defendants' Mesh Products were free of manufacturing defects.

163. Prior to the manufacture, sale, and distribution of the Mesh Products, Defendants knew, or should have known, that the Mesh Products were defectively manufactured.

164. The Mesh Products used for their intended purpose and the manufacturing defects could not have been and were not discovered through the exercise of due care.

165. At all relevant times, there existed safer and more or equally effective alternative treatment methods.

166. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging, selling and/or distributing the defectively manufactured Mesh Products.

167. As a direct and proximate result of Defendants' defective manufacture of the Mesh Products, Plaintiffs have sustained permanent injuries and damages as set forth herein.

Count IV: Strict Liability – Failure to Warn

168. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

169. At all relevant times, Defendants' Mesh Products were not reasonably safe for their intended uses and were defective as a matter of law due to their lack of appropriate and necessary warnings.

170. Amongst other failures, Defendants did not adequately warn that:

- a. The Mesh Products cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- b. The materials used in the Mesh Products cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- c. The design of the Mesh Products and/or implantation kits requires implantation into and through an area of the body with high levels of bacteria that can adhere to the mesh and/or can injure nerves in the pelvic region causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- d. The design of the Mesh Products increases the likelihood of contracture, shrinkage, erosion, and/or folding causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- e. The design of the Mesh Product increases the risk of movement, elongation, and/or deformity after implantation causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue

breakdown, pain, disability, and/or other resulting injuries and sequelae;

- f. The design of the Mesh Products increases the risk of improper mating to the delicate and sensitive areas where they are implanted causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- g. The design of the Mesh Products increases the risk of degradation, erosion, and/or fragmentation causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- h. The disintegration of and hyper-inflammatory responses to the collagen components of the Mesh Products cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae;
- i. The hardening of the Mesh Products following implantation cause chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae; and/or
- j. The design of the Mesh Products creates a non-anatomic condition in the pelvis causing chronic immune, inflammatory, and fibrotic reactions, infections, tissue breakdown, pain, disability, and/or other resulting injuries and sequelae.

171. At all relevant times, Defendants knew or should have known that the warnings they provided regarding the risks associated with the use of the Mesh Products were inadequate.

172. Plaintiffs, and the Plaintiffs' healthcare providers, did not have the same knowledge as Defendants, and no adequate warning or other clinically relevant information was communicated to Plaintiffs or Plaintiffs' healthcare providers to adequately apprise them of the risks described herein.

173. Defendants had a continuing duty to provide warnings regarding the risks and dangers associated with the Mesh Products as it became or should have become available to Defendants.

174. Defendants knew or should have known that consumers, and Plaintiffs specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures to provide adequate warnings.

175. Through both omissions and affirmative misstatements, Defendants misled Plaintiffs, Plaintiffs' treating physicians, the medical community, and the general public about the risks and benefits of the Mesh Products, which resulted in injury to Plaintiffs.

176. Despite having inadequate warnings, Defendants continued to aggressively manufacture, market, promote, distribute, and sell the Mesh Products, even after they knew or should have known of the unreasonable risks of from the Mesh Products.

177. By failing to provide Plaintiffs and the Plaintiff's physicians with adequate, clinically relevant information, and data and warnings regarding the adverse health risks associated with the Mesh Products, Defendants breached their duty of reasonable care and safety.

178. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging, selling and/or distributing the Mesh Products with inadequate warnings.

179. As a direct and proximate result of Defendants' failure to warn, Plaintiffs have sustained permanent injuries and damages as set forth herein.

Count V: Breach of Implied Warranties

180. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

181. Defendants made implied assurances that the Mesh Products were safe and reasonably fit for their intended purposes.

182. Defendants are liable to Plaintiffs for the breach of implied warranties with respect to Defendants' Mesh Products.

183. Defendants, by directly and indirectly advertising, marketing, and promoting the Mesh Products, and by placing the Mesh Products into the stream of commerce knowing that the Mesh Products would be implanted in women, impliedly warranted that the Mesh Products were safe, merchantable, effective, and reasonably fit for their intended purposes.

184. Defendants knew or should have known that users of the Mesh Products would reasonably rely on these implied warranties.

185. Plaintiffs' use of Defendants' Mesh Products was consistent with the purposes for which Defendants directly and indirectly advertised, marketed, and promoted the Mesh Products.

186. Defendants breached these implied warranties because the Mesh Products implanted in Plaintiffs were unreasonably dangerous and defective and not as Defendants had represented.

187. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs have sustained permanent injuries and damages as set forth herein.

Count VI: Gross Negligence

188. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

189. At all relevant times, Defendants failed to perform adequate testing to ensure that the Mesh Products were reasonably safe for implantation in patients, including Plaintiffs.

190. At all relevant times Defendants designed, patented, tested, manufactured, labeled, marketed, sold, and distributed the Mesh Products with actual and/or constructive knowledge that the Mesh Products can shrink, disintegrate and/or degrade inside the body, and cause the other serious medical problems and resulting sequelae.

191. Defendants consciously disregarded reports from regulatory agencies, patients, the medical community, and individual health care providers that the Mesh Products did not perform as intended and that the Mesh Products were associated with increased risks of serious injuries and resulting sequelae.

192. Rather than performing adequate testing to determine the cause of these injuries, or to rule out defects with the Mesh Products, Defendants chose to continue marketing and selling the Mesh Products, fraudulently, intentionally, and/or recklessly misrepresenting, concealing, and/or suppressing material information regarding the safety and efficacy of the Mesh Products.

193. Defendants knew or should have known that the Mesh Products were unreasonably dangerous in light of their risks.

194. Defendants knew and consciously disregarded the fact that the Mesh Products caused debilitating injuries and related sequelae with significantly greater frequency than feasible alternative treatment methods.

195. Defendants fraudulently, willfully, maliciously, oppressively, consciously, intentionally, and/or recklessly misrepresented, concealed, and/or suppressed material

information regarding the safety and efficacy of the Mesh Products so as to minimize the perceived risk of injuries caused by the Mesh Products.

196. Defendants knew or should have known of the Mesh Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs.

197. Defendants continue to fraudulently, willfully, maliciously, oppressively, consciously, intentionally, and/or recklessly misrepresent conceal, and/or suppress material information regarding the safety and efficacy of the Mesh Products from the public to promote continued and increased sales of the Mesh Products.

198. As a direct and proximate result of Defendants' gross negligence, Plaintiffs suffered, and continue to suffer, injuries and damages, as set forth herein.

199. Furthermore, Defendants have been unjustly enriched as a result of their gross negligence. In addition to the causes of action set forth herein, Plaintiffs assert a claim of unjust enrichment.

200. Defendants' actions constitute a willful, despicable, fraudulent, malicious, oppressive, reckless, and conscious disregard for the rights of Plaintiffs and the public, justifying an award of punitive damages.

VII.

Plaintiffs' Damages

201. Plaintiffs incorporate all of the above paragraphs as if set forth in full herein.

202. As a direct and proximate result of Defendants' conduct and Defendants' Mesh Products, Plaintiffs have suffered severe injuries and damages in an amount in excess of the jurisdictional minimum of this Court.

203. As a direct and proximate result of Defendants' conduct, Plaintiffs suffered physical injuries and damages. Further, the Plaintiffs have sustained in the past, and will sustain in the future, pain and suffering, mental anguish, emotional distress, disfigurement, physical impairment, embarrassment and humiliation, psychological injury, a reasonable and traumatic fear of an increased risk of additional injuries, progression of existing conditions, and other serious injury and loss.

204. As a direct and proximate result of Defendants' conduct and/or Defendants' Mesh Products, Plaintiffs have incurred, and will continue to incur for the foreseeable future, medical, nursing, diagnostic, hospital, pharmaceutical, rehabilitative, and other related costs and expenses for Plaintiffs' treatment and care, along with lost wages, lost earning capacity, and other damages.

205. As Defendants' actions constitute a willful, despicable, fraudulent, malicious, oppressive, reckless, and conscious disregard for the rights of Plaintiffs and the public justifying an award of punitive damages, Plaintiffs sue for an additional amount as exemplary damages.

206. Accordingly, Plaintiffs sue for special, compensatory, and punitive damages, cost of court, reasonable attorneys' fees, pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf, and for all other relief to which they each may be entitled in law and/or equity.

VIII.

Jury Demand

207. Plaintiffs' respectfully request trial by jury.

IX.

Conclusion

Plaintiffs respectfully request trial by jury and that the Court grant them the following relief against Defendants, both jointly and severely, on all counts of this Complaint, including:

- a. Special and compensatory damages representing fair, just, and reasonable compensation for their respective common law and statutory claims in excess of the jurisdictional minimum of this Court;
- b. Past and future lost wages and lost earning capacity;
- c. Past and future medical expenses;
- d. Past and future disfigurement, physical impairment, mental anguish, pain, and suffering;
- e. Punitive damages;
- f. Cost of court;
- g. Reasonable attorneys' fees;
- h. Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf; and
- i. Such other relief as is deemed just and appropriate.

Respectfully submitted,

/s/ KURT B. ARNOLD

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